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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,363	06/15/2001	Eugene J. Alexander	STAN-144/01US	6739

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

T.M.K.

Office Action Summary	Application No. 09/882,363	Applicant(s) ALEXANDER ET AL	
	Examiner Jonathan ML Foreman	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-43, 45-47, 49, 51, 52 and 54-68 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 36, 42, 43, 45-47, 49, 51, 52 and 54-68 is/are rejected.
 7) ☒ Claim(s) 37-41 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/2/04; 5/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

New grounds of rejection are contained within this Office Action. Accordingly this action has been made Non-Final.

Information Disclosure Statement

The information disclosure statements filed 12/2/04 and 5/11/05 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. The information disclosure statements have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 42, 43, 61 and 64 are rejected under 35 U.S.C. 102(a) as being anticipated by Eckstein et al. (1998 AJR 170; 593 – 597).

In regards to claims 36, 42, 43, 61 and 64, Eckstein et al. discloses assessing the change of cartilage in a living human knee joint including determining the thickness or volume of a region of cartilage at an initial time and a later time; determining the change in thickness or volume of the cartilage between the initial and later time (Page 597, Col. 1, 1st complete paragraph); electronically transferring an electronically generated image from a transferring device to a receiving device located distant the transferring device, receiving the transferred image at a distant location; and converting the transferred image to a degeneration pattern (Page 594, “Digital Image Processing”).

Claims 49, 51 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,320,102 to Paul et al.

In regards to claims 49, 51 and 52, Paul et al. discloses making a three-dimensional map of joint cartilage (Col.4, lines 31 – 34; Col. 5, lines 28 – 32) of a human knee joint including measuring a detectable biochemical component selected from the group consisting of glycosaminoglycan, sodium, water and hyaluronic acid (Col. 8, line 52 – Col. 9, line 18); mapping the amounts of the biochemical component in three dimensions (Col.4, lines 31 – 34; Col. 5, lines 28 – 32; Col. 10, lines 40 - 64); determining the relative amounts of the biochemical component and determining abnormal joint cartilage by identifying the areas having altered amounts of the biochemical component present (Col. 11, lines 27 **60/112989** – 42).

Claims 36, 42, 43, 45 – 47 and 61 – 68 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,560,476 to Pelletier et al.

In reference to claims 36, 42, 43, 45 – 47 and 61 – 68, Pelletier et al. discloses a method of assessing the change of thickness, width, area and volume of cartilage in a human knee (Col. 9, lines 48 – 51) using MRI imaging including: determining the thickness of the cartilage comprising normal and diseased cartilage at an initial time, at a later time and determining the change in the thickness between the initial and later times; transferring the electronically generated image from a transferring device to a receiving device; receiving the transferred image at the distant location; and converting the transferred image to a degeneration pattern (Col. 14, line 13 – Col. 15, line 23). Pelletier et al. discloses placing external markers on the skin overlaying the bone on either side of the joint (Col. 4, lines 10 – 15). The MRI technique employs spoiled gradient echo (Col. 11, line 39) and obtains a series of two-dimensional views of the joint, which are integrated to give a three-dimensional image.

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Claims 57 - 60 are rejected under 35 U.S.C. 102(a) as being anticipated by Kshirsager et al. (Investigative Radiology, vol. 33, no. 5).

In regards to claims 57 – 60, Kshirsager et al. discloses a method of estimating a change of cartilage in a knee joint (289, Col. 2) including defining a 3D object coordinate system at an initial time T1; identifying a region of cartilage defect or diseased cartilage within the 3D object coordinate system; defining a volume of interest around the region of the cartilage defect or diseased cartilage whereby the volume of interest is equal to or larger than the cartilage defect, but does not encompass the entire articular cartilage (294, Col. 2, Focal Cartilage Volume); defining a 3D object coordinate system of the joint at a second timepoint, T2; placing the identically-sized volume of interest into the 3D coordinate system at timepoint T2 using the object coordinates of the volume of interest at timepoint T1; and measuring any differences in cartilage within the volume of interest at timepoints T1 and T2 (289, Col. 2; 290, Col. 2, Materials and Methods; Page 296, table 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45 – 47 and 65 – 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckstein et al. in view of U.S. Patent No. 5,427,099 to Adams.

In regards to claims 45 – 47, 65 and 68, Eckstein et al. discloses assessing the change of cartilage in a living human knee joint including determining the thickness or volume of a region of cartilage at an initial time and a later time using a magnetic imaging technique (MRI); determining

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the change in thickness or volume of the cartilage between the initial and later time (Page 597, Col. 1, 1st complete paragraph). The MRI technique disclosed by Eckstein et al. creates a three-dimensional image which inherently involves first obtaining a series of two-dimensional views that are integrated to create the three-dimensional image. Eckstein et al. discloses the MRI technique employing a gradient echo, spin echo, fast-spin echo, driven equilibrium forier transform, spoiled gradient echo or steady state free precession technique (Page 594, "Subjects and Methods").

However, Eckstein et al. fails to disclose placing external markers on the skin overlying the bone on either side of the joint. Adams discloses a marker for use with an MRI to be placed on the skin of an area of interest (Col. 3, lines 44 – 52). It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Eckstein et al. to include the step of applying a marker or markers as taught by Adams on either side of the joint locate the area of concern, allowing for a narrower focus in the MRI (Col. 3, lines 52 – 57).

In regards to claims 66 and 67, Eckstein et al. in view of Adams discloses determining the thickness or volume of cartilage and determining a change in thickness or volume of cartilage (Page 597, Col. 1, 1st complete paragraph). However, Eckstein et al. in view of Adams fails to disclose determining the width or area of cartilage or determining the change in width or area of cartilage. However, it is well known in the art that width and area of cartilage are desirable measurements commonly made using MRI imaging. It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Eckstein et al. in view of Adams to include the step of measuring and determining the change in width or area of cartilage if desired.

Claims 54 – 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,320,102 to Paul et al. as applied to claim 49 above, and further in view of U.S. Patent No. 5,427,099 to Adams.

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In regards to claims 54 – 56, Paul et al. discloses an MRI technique to create a three-dimensional image which inherently involves first obtaining a series of two-dimensional views that are integrated to create the three-dimensional image. Paul et al. discloses the MRI technique employing a gradient echo, spin echo, fast-spin echo, driven equilibrium forier transform, spoiled gradient echo or steady state free precession technique (Page 594. “Subjects and Methods”). However, Paul et al. fails to disclose placing external markers on the skin overlying the bone on either side of the joint. Adams discloses a marker for use with an MRI to be placed on the skin of an area of interest (Col. 3, lines 44 – 52). It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Paul et al. to include the step of applying a marker or markers as taught by Adams on either side of the joint locate the area of concern, allowing for a narrower focus in the MRI (Col. 3, lines 52 – 57).

Claims 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckstein et al.

In regards to claims 62 and 63, Eckstein et al. discloses determining the thickness or volume of cartilage and determining a change in thickness or volume of cartilage (Page 597, Col. 1, 1st complete paragraph). However, Eckstein et al fails to disclose determining the width or area of cartilage or determining the change in width or area of cartilage. However, it is well known in the art that width and area of cartilage are desirable measurements commonly made using MRI imaging. It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Eckstein et al to include the step of measuring and determining the change in width or area of cartilage if desired.

Response to Arguments

Applicant's arguments filed 8/2/04 have been fully considered but they are not persuasive.

In regards to Eckstein et al., Applicant asserts that the claims are drawn to methods of assessing the change in cartilage over time by determining a degeneration pattern, and that Eckstein et al. fails to disclose comparing images from the same subject over time to create a degeneration pattern. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., comparing images from the same subject over time to create a degeneration pattern) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In regards to U.S. Patent No. 5,320,102 to Paul, Applicant asserts that Pual fails to disclose the claimed invention because the method of making three-dimensional cartilage maps from the information does not include information such regarding proteoglycan content. However, the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.");< *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves

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"the claim open for the inclusion of unspecified ingredients even in major amounts"). As such, the fact that the claimed invention does not include information regarding proteoglycan content is irrelevant. However, the claim recites the biochemical component being glycosaminoglycan, which is an integral part of proteoglycan.

Allowable Subject Matter

Claims 37 – 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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